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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,408	07/15/2005	Yasuaki Ito	105577.0004	8596

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,408	ITO ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58 and 67-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58 and 67-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The preliminary amendment of 7/15/05 has been entered in full. Claims 59-66 are canceled. Claims 2-40, 42-45, 52-58, 67-74, 76 and 77 are amended.

Claims 1-58 and 67-77 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 3, 14 and 67-70, drawn to a method of screening for a compound that modulates binding of a receptor to a fatty acid comprising using said receptor and fatty acid, or to a method for confirming that a drug binds to said receptor.

Group II, claims 2 and 4, drawn to kits comprising a receptor and a fatty acid that binds said receptor, and kits comprising a receptor and a compound that modulates binding of said receptor and fatty acid.

Group III, claims 5-13, 15-18 and 45-50, drawn to an agent comprising a compound that modulates the binding of a receptor and a fatty acid.

Group IV, claims 19-25, 33-36 and 73-77, drawn to a polynucleotide encoding a GPCR or a complement of said polynucleotide, vectors and cells comprising said GPCR, and a method of producing said GPCR using a host cell transformed with a vector.

Group V, claims 26-32, drawn to an antibody that binds to a GPCR.

Group VI, claims 37-40, drawn to an agent that increases the expression level of a GPCR.

Group VII, claims 41-44, drawn to an agent comprising a compound that decreases the expression level of a GPCR.

Group VIII, claims 51-54, in so far as they are drawn to a method of treatment comprising administering a GPCR.

Group IX, claims 51-58, in so far as they are drawn to a method of treatment comprising administering a polynucleotide encoding a GPCR.

Group X, claims 51-54, in so far as they are drawn to a method of treatment comprising administering an agonist of a GPCR.

Group XI, claims 55-58, in so far as they are drawn to a method of treatment comprising administering an antagonist of a GPCR.

Group XII, claim 71, drawn to a pharmaceutical comprising the combination of an agonist or antagonist to a GPCR, and/or a compound that changes the expression level of said GPCR, and/or a drug.

Group XIII, claim 72, drawn to an isolated GPCR consisting of SEQ ID NO: 8.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIII appears to be that they all relate to a fatty acid-binding GPCR of SEQ ID NO: 1 (human), 3 (murine) or 8 (rat). The earliest date to which the instant application claims U.S. priority is 1/15/2004, and the earliest date to which the instant application claims foreign priority is 1/17/2003.

However, U.S. Patent 6,395,877, published 5/28/2002 (reference A2 on the 7/15/05 IDS), teaches the "14237 receptor" which is a "novel G-protein coupled receptor". The '877 patent discloses the sequence of the human 14237 receptor as SEQ ID NO: 1, which is 361 amino acids in length. This sequence is identical to the 361 amino acid long sequence of instant SEQ ID NO: 1.

Therefore, the technical feature linking the inventions of Groups I-XIII does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Elections of species

In addition to the above restriction requirement, two election of species are required as follows:

(1) This application contains claims directed to more than one species of GPCR the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) SEQ ID NO: 1 (human), (b) SEQ ID NO: 2 (mouse) and (c) SEQ ID NO: 8 (rat).

The claims are deemed to correspond to the species in the following manner:

Claims 1-58 and 67-72 recite each of the species as part of Markush-type group, or depend from such a claim. Claims 72-77 are limited to species (c).
The following claim(s) are generic: none.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each GPCR is composed a different sequence of amino acids that results in a distinct structure for the receptor. Lack of unity is shown because these proteins lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) This application contains claims directed to more than one species of disorder the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: diabetes mellitus, hyperlipemia, arteriosclerosis, angina pectoris, myocardial infarction, stress, Cushing's disease, infectious disease, secondary adrenocortical insufficiency, peptic ulcer, diabetes mellitus, mental disorder, cataract, glaucoma, tuberculous disease, hypertension, Cushing's syndrome, adrenocortical atrophy, obesity, rheumatism, systemic lupus erythematosus, polymyositis, rheumatic fever, scleroderma, kidney disease, bronchial asthma, pulmonary tuberculous pleuritis, sarcoidosis, diffuse interstitial pneumonia, ulcerative colitis, cholestatic acute hepatitis, fulminant hepatitis, chronic hepatitis, cirrhosis, encephalomyelitis, peripheral neuritis, multiple sclerosis, myasthenia gravis, facial paralysis, hemolytic anemia, granulocytosis, purpura, aplastic anemia, leukemia, malignant lymphoma, acute or chronic adreno-cortical insufficiency, adrenogenital syndrome, malignant exopthalmos due to thyroid gland disease, ACTH isolated deficiency, urticaria, eczema, dermatitis, herpes zoster, psoriasis, drug allergy, anaphylactic shock, impaired glucose tolerance, ketosis, acidosis, diabetic neuropathy, diabetic nephropathy, diabetic retinopathy, hyperlipemia, arteriosclerosis, angina

pectoris, myocardial infarction, sexual dysfunction, obesity, pituitary dysfunction, cancer, deficits in memory and learning, pancreatic exhaustion, hypoglycemia, insulin allergy, lipotoxicity, fatty atrophy, cancerous cachexia, hyper-insulinemia, hyperglycemia, disorder caused by high FFA flux, hypertriglyceridemia, fatty liver, dysfunction of heat production, cholelithiasis, eating disorder, secretion disorders of intestinal hormones, circulatory disease and ACTH-producing tumor.

The claims are deemed to correspond to the species in the following manner: Claims 6, 9, 13, 15, 18, 19, 22, 23, 25, 29, 30, 32, 36, 37, 40, 44, 46, 49, 51, 54, 58 and 67-71 each recite two or more of the species as part of a Markush type group, or depend from such a claim. Claim 7, 11, 16, 20, 27, 31, 34, 38, 42, 47, 52 and 56 are limited to the species of stress; claim 9, 33, 41 and 55 are limited to the species of obesity. The following claim(s) are generic: 1-5, 8, 12, 14, 17, 21, 24, 26, 28, 35, 39, 43, 45, 48, 50, 53, 57 and 72-77.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disorder has a different etiology and molecular dysfunction within specific tissues of the body. Lack of unity is shown because these disorders lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is required, in reply to this action, to elect a single species of (1) GPCR and (2) disorder, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are

added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647